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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,089	03/25/2004	Andrew R. Marks	19240-596 US1	7653
56949 7590 08/05/2009 WilmerHale/Columbia University 399 PARK AVENUE NEW YORK, NY 10022				
EXAMINER				
PACKARD, BENJAMIN J				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
08/05/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/809,089

**Applicant(s)**

MARKS ET AL.

**Examiner**

Benjamin Packard

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13, 15, 17, 18, 25, 26, 29, 30, 33, 35, 43, 49-52, 55-60, 62, 63 and 66-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 59, 60, 62, 63, 66-69, 72 and 73 is/are allowed.
- 6) ☒ Claim(s) 13, 15, 17, 18, 25, 29, 30, 33, 35, 43, 49-52, 55-58, 70 and 71 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

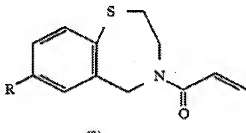
Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2pgs (4/03/09), 2pgs (5/13/09), 2pgs (6/15/09).

### DETAILED ACTION

Applicants' arguments, filed 04/03/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *Election/Restrictions*

Because Applicants amended around the prior elected species, Examiner now expands examination to the following species:



where R is methoxy (instant S27).

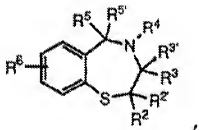
### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 13, 15, 17, 18, 25, 29, 30, 33, 35, 43, 49-52, 55-58, 70, and 71** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bondilell et al (WO

93/00095, see IDS dated 5/13/09) in view of Kaneko et al (US 5,416,066, see IDS dated 11/26/04).

Bondilell et al teaches the class of compounds of general formula

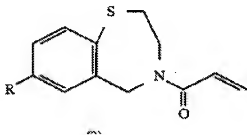


(claim 4), where R4 may be oxoalkenyl and R6

may be alkoxy (claim 1). The compounds are disclosed to be useful for the treating stroke, transient ischemia attacks and myocardial infarctions (pg 5 lines 9-25). Dosage is in the range of 0.4 to about 200 mg/kg/day (pg 38 lines 15-20).

Bondilell et al does not teach the instantly elected species as a preferred embodiment.

Kaneko et al teaches the compound



(col 3 lines 20-30) where R is C1-C3 alkoxy (col 2

line 20).

Kaneko et al does not teach administration of the disclosed compound.

It would be obvious to one of ordinary skill in the art, when practicing the method disclosed in the primary reference to use compounds already known which fall within

the disclosed genus, such as the compound taught in the secondary reference. Where the compound of the secondary reference is structurally similar to embodiments disclosed in the primary reference and falls within the genus of compounds disclosed to have a specific activity, the compound would reasonably be expected to have similar activity.

Note, with regards to the preambles of the independent claims, while the prior art does not specifically disclose the mechanism or specific diseases to reduce the risk of, if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Here, the compound made obvious by the prior art is the same as instantly claimed, therefore where the same active step instantly claimed, i.e. administering an effective amount of the agent to a subject, is met, then it would naturally flow that the binding of FKB12.6 to RyR2 would increase and as such, the risk of sudden cardiac death would occur. Further, while claims 14 and 30 appear to limit the patient population, the claims are directed to subjects who are "at risk" of developing a condition selected from the claimed list. Given all people are at some risk of developing heart conditions, such as limitation is read broadly to include all people.

#### ***Allowable Subject Matter***

**Claim 26** stands objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Claims 59, 60, 62, 63, 66-69, 72, and 73** are allowed

Bondillel et al is the closest prior art to claim 26 and is discussed above, but the R group is only disclosed in the prior art only includes oxoalkyls-C1-C3 which may be substituted with –OH. The prior art does not suggest the substitution of multiple ketone groups. Additionally, the prior art does not teach the treatment of a patient who has cardiac arrhythmia.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 5/13/09 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612